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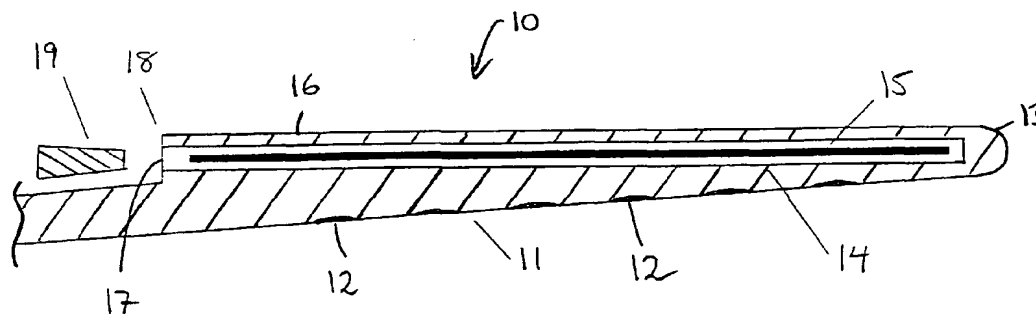
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(54) Title: COCHLEAR IMPLANT ELECTRODE ARRAY



(57) Abstract: A cochlear implant electrode assembly (10) comprising an elongate electrode carrier member (11), a bioresorbable stiffening element (15) and an outer layer (16) surrounding the stiffening element (15). The carrier member (11) is made of a resiliently flexible first material and has a plurality of electrodes (12) mounted thereon and has a first configuration selected to allow it to be inserted into an implantee's cochlea, and at least a second configuration wherein it is curved to match a surface of the cochlea. The bioresorbable stiffening element (15) has a configuration selected for biasing the elongate member (11) into the first configuration and is made of a second material relatively stiffer than the first material and which dissolves or softens on exposure to cochlear fluids to permit the elongate member (11) to at least approach or adopt the second configuration. The outer layer (16) surrounding the stiffening element (15) is made of a material sufficiently resiliently flexible to allow the elongate member (11) to at least approach or adopt the second configuration. The outer layer (16) has a first rate of cochlear fluid ingress therethrough and has at least one fluid ingress means (21) formed therein. The rate of cochlear fluid ingress through the fluid ingress means (21) is greater than the first rate of cochlear fluid ingress through the outer layer (16).

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

"Cochlear implant electrode array"

Field of the Invention

The present invention relates to an implantable device and, in particular, to an implantable cochlear electrode incorporating a bioresorbable
5 stylet.

Background of the Invention

Hearing loss, which may be due to many different causes, is generally of two types, conductive and sensorineural. Of these types, conductive hearing loss occurs where the normal mechanical pathways for sound to
10 reach the hair cells in the cochlea are impeded, for example, by damage to the ossicles. Conductive hearing loss may often be helped by use of conventional hearing aid systems, which amplify sound so that acoustic information does reach the cochlea and the hair cells.

In many people who are profoundly deaf, however, the reason for
15 deafness is sensorineural hearing loss. This type of hearing loss is due to the absence of, or destruction of, the hair cells in the cochlea which transduce acoustic signals into nerve impulses. These people are thus unable to derive suitable benefit from conventional hearing aid systems, because there is damage to or absence of the mechanism for nerve impulses to be generated
20 from sound in the normal manner.

It is for this purpose that cochlear implant systems have been developed. Such systems bypass the hair cells in the cochlea and directly deliver electrical stimulation to the auditory nerve fibres, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing
25 sensation normally delivered to the auditory nerve. US Patent 4532930, the contents of which are incorporated herein by reference, provides a description of one type of traditional cochlear implant system.

Cochlear implant systems have typically consisted of two key components, namely an external component commonly referred to as a
30 processor unit, and an implanted internal component commonly referred to as a stimulator/receiver unit. Traditionally, both of these components have cooperated together to provide the sound sensation to an implantee.

The external component has traditionally consisted of a microphone for detecting sounds, such as speech and environmental sounds, a speech
35 processor that converts the detected sounds and particularly speech into a

coded signal, a power source such as a battery, and an external antenna transmitter coil.

The coded signal output by the speech processor is transmitted transcutaneously to the implanted stimulator/receiver unit situated within a recess of the temporal bone of the implantee. This transcutaneous transmission occurs through use of an inductive coupling provided between the external antenna transmitter coil which is positioned to communicate with an implanted antenna receiver coil provided with the stimulator/receiver unit. This communication serves two essential purposes, firstly to transcutaneously transmit the coded sound signal and secondly to provide power to the implanted stimulator/receiver unit. Conventionally, this link has been in the form of a radio frequency (RF) link, but other such links have been proposed and implemented with varying degrees of success.

The implanted stimulator/receiver unit typically included the antenna receiver coil that receives the coded signal and power from the external processor component, and a stimulator that processes the coded signal and outputs a stimulation signal to an intracochlea electrode assembly which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected sound.

The external componentry of the cochlear implant has been traditionally carried on the body of the implantee, such as in a pocket of the implantee's clothing, a belt pouch or in a harness, while the microphone has been mounted on a clip mounted behind the ear or on a clothing lapel of the implantee.

More recently, due in the main to improvements in technology, the physical dimensions of the speech processor have been able to be reduced allowing for the external componentry to be housed in a small unit capable of being worn behind the ear of the implantee. This unit has allowed the microphone, power unit and the speech processor to be housed in a single unit capable of being discretely worn behind the ear, with the external transmitter coil still positioned on the side of the user's head to allow for the transmission of the coded sound signal from the speech processor and power to the implanted stimulator unit.

With continuing future technological advancements it will be possible to provide a cochlear implant system which is totally implanted within the head of the user and requires no external devices to operate. The microphone

will be implanted within the user as well as a power source, so that there will be no need to require an external link for the device to operate, at least for a period of time.

Together with improvements in available technology much research
5 has been undertaken in the area of understanding the way sound is naturally processed by the human auditory system. With such an increased understanding of how the cochlea naturally processes sounds of varying frequency and magnitude, there is a need to provide an improved cochlear implant system that delivers electrical stimulation to the auditory nerve in a
10 way that takes into account the natural characteristics of the cochlea.

It is known in the art that the cochlea is tonotopically mapped. In other words, the cochlea can be partitioned into regions, with each region being responsive to signals in a particular frequency range. This property of the cochlea is exploited by providing the electrode assembly with an array of
15 electrodes, each electrode being arranged and constructed to deliver a cochlea-stimulating signal within a preselected frequency range to the appropriate cochlea region. The electrical currents and electric fields from each electrode stimulate the cilia disposed on the modiola of the cochlea. Several electrodes may be active simultaneously.

20 It has been found that in order for these electrodes to be effective, the magnitude of the currents flowing from these electrodes and the intensity of the corresponding electric fields, are a function of the distance between the electrodes and the modiola. If this distance is relatively great, the threshold current magnitude must be larger than if the distance is relatively small.
25 Moreover, the current from each electrode may flow in all directions, and the electrical fields corresponding to adjacent electrodes may overlap, thereby causing cross-electrode interference. In order to reduce the threshold stimulation amplitude and to eliminate cross-electrode interference, it is advisable to keep the distance between the electrode array and the modiola as
30 small as possible. This is best accomplished by providing the electrode array in the shape which generally follows the shape of the modiola. Also, this way the delivery of the electrical stimulation to the auditory nerve is most effective as the electrode contacts are as close to the auditory nerves that are particularly responsive to selected pitches of sound waves.

35 In order to achieve this electrode array position close to the inside wall of the cochlea, the electrode needs to be designed in such a way that it

assumes this position upon or immediately following insertion into the cochlea. This is a challenge, as the array needs to be shaped such that it assumes a curved shape to conform with the shape of the modiola and must also be shaped such that the insertion process causes minimal trauma to the sensitive structures of the cochlea. In this sense it has been found to be desirable for the electrode array be generally straight during the insertion procedure.

Several procedures have been adopted to provide an electrode assembly that is relatively straightforward to insert while adopting a curved configuration following insertion in the cochlea. In one case, a platinum wire stylet is used to hold a pre-curved electrode array in a generally straight configuration up until insertion. Following insertion, the platinum stylet is withdrawn allowing the array to return to its pre-curved configuration.

In another development, a bimetallic filament (such as nickel/titanium) or a shape memory alloy (such as an alloy of nickel and titanium) is positioned in the electrode assembly and used to again hold a pre-curved electrode array in a generally straight configuration while the array is at about room temperature. On insertion into the body and exposure to body temperature, the alloy or filament bends into a pre-selected curved configuration.

In a still further arrangement, a longitudinal element that is arranged on one side of the array and constructed to change its dimension on insertion can be utilised. For example, the longitudinal element could include a hydrogel, such as polyacrylic acid (PAA) or polyvinyl alcohol (PVA), which expands after insertion by absorbing water from the cochlear fluid.

In developing such electrode array designs, it is of great importance that the design be constructed to minimise potential damage to sensitive structures in the cochlear on insertion and placement. Each of the above constructions suffer from a number of disadvantages in this regard.

Still further, it has been proposed to straighten pre-curved electrode arrays using inserted longitudinal elements or surrounding sheaths formed from bioresorbable materials that dissolve or soften on implantation. A disadvantage with use of such bioresorbable materials is that, due to the generally wet nature of the surgical environment, the polymer can dissolve or soften before the electrode array is appropriately positioned, causing difficulties in placement and insertion procedures.

The present invention is directed to an electrode assembly adapted to overcome some of the difficulties of prior art electrode assemblies.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

10 Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

The present invention relates to an implantable tissue stimulating device having a first configuration prior to and at least on commencement of insertion into an implantee's body and adapted to adopt at least a second configuration following insertion.

20 According to one aspect, the present invention is an implantable tissue-stimulating device comprising:

an elongate member having a plurality of electrodes mounted thereon and having a first configuration selected to allow said member to be inserted into an implantee's body and at least a second configuration wherein said elongate member is adapted to apply a preselected tissue stimulation with the electrodes, said elongate member being made of a resiliently flexible first material;

a bioresorbable stiffening element having a configuration selected for biasing said elongate member into said first configuration, said stiffening element being made of a second material relatively stiffer than said first material and which dissolves or softens on exposure to a fluid to permit said elongate member to at least approach or adopt said second configuration; and

an outer layer surrounding the stiffening element, the layer being made of a material sufficiently resiliently flexible to allow said elongate member to at least approach or adopt said second configuration, the outer layer having a first rate of fluid ingress therethrough and having at least one fluid ingress

means formed therein, the rate of fluid ingress through the fluid ingress means being greater than the first rate of fluid ingress through the outer layer.

In a preferred embodiment, the second configuration of the elongate member is curved. More preferably, the elongate member adopts a spiral

5 configuration when in the second configuration.

In a further embodiment, the fluid is a saline solution. In another embodiment, the fluid is a body fluid of the implantee.

According to a second aspect, the present invention is a cochlear implant electrode assembly comprising:

10 an elongate electrode carrier member having a plurality of electrodes mounted thereon and having a first configuration selected to allow said member to be inserted into an implantee's cochlea and at least a second configuration wherein said elongate member is curved to match a surface of said cochlea, said elongate member being made of a resiliently flexible first
15 material;

a bioresorbable stiffening element having a configuration selected for biasing said elongate member into said first configuration, said stiffening element being made of a second material relatively stiffer than said first material and which dissolves or softens on exposure to cochlear fluids to
20 permit said elongate member to at least approach or adopt said second configuration; and

an outer layer surrounding the stiffening element, the layer being made of a material sufficiently resiliently flexible to allow said elongate member to at least approach or adopt said second configuration, the outer layer having a
25 first rate of cochlear fluid ingress therethrough and having at least one fluid ingress means formed therein, the rate of cochlear fluid ingress through the fluid ingress means being greater than the first rate of cochlear fluid ingress through the outer layer.

The elongate member is preferably preformed from a plastics material with memory and is preformed to the second configuration. The elongate
30 member preferably has a first end that is firstly inserted into the implantee.

In a preferred embodiment, the first configuration is preferably substantially straight. More preferably, the first configuration is straight.

In a preferred embodiment, the elongate member is formed from a
35 suitable biocompatible material. In one embodiment, the material can be a

silicone, such as Silastic MDX 4-4210. In another embodiment, the elongate member can be formed from a polyurethane.

In a further embodiment, the elongate member can have a resiliently flexible tip member extending forwardly from the first end of the body. The tip member preferably has a distal end and a proximal end. The tip member can have a stiffness that is relatively less stiff than said stiffening element. The tip member can further be formed of a material that is substantially the same or the same stiffness as the body of the elongate member. In another embodiment, the tip member can be formed of a material that is relatively less stiff than at least a portion of the elongate member. In a further embodiment, the tip member can be formed of a material that undergoes a change in stiffness, preferably a decrease in stiffness, on insertion into the body, such as the cochlea.

In a further embodiment, the stiffness of the tip member can vary along at least a portion of its length from its distal end to its proximal end. In one embodiment, the stiffness of the tip member can vary over the entire length of the tip member or only a portion thereof. The stiffness can increase from the distal end to the proximal end. In one embodiment, the stiffness of the tip member over said portion or its length can increase gradually from its distal end towards to the proximal end. The increase in stiffness can be substantially smooth or increase in a stepwise fashion.

In a further embodiment, the tip member can be formed of the same material as the body of the elongate member. In another embodiment, the tip member can be formed of a different material to that of the body of the elongate member. The tip member can be comprised of an inner relatively stiff core of material having a tapered end, with at least the tapered end being overlaid by a relatively flexible material that extends beyond the tapered end of the core material so that the tip member undergoes a gradual decrease in flexibility in the region of the tapered end of the core moving away from the distal end.

The tip member can be formed separately to the body of the elongate member and mounted thereto. For example, the tip member can be adhered to the first end of the body of the elongate member. In another embodiment, the tip member can be integrally formed with the body of the elongate member. The tip member can be formed from a silicone material. In another

embodiment, the tip member can be formed of an elastomeric material, such as polyurethane.

In another embodiment, the tip member can have a plurality of metallic particles dispersed therethrough. The metallic particles can be substantially
5 evenly dispersed through the tip member. Alternatively, the metallic particles can be non-evenly dispersed throughout the tip member. In one embodiment, the metallic particles can increase in density away from the distal end towards the proximal end of the tip member. By varying the density of the metallic particles, it is possible to vary the relative stiffness of
10 the tip member.

The metallic particles preferably comprise a biocompatible material, such as platinum. The particles can be substantially spherical or spherical. It will be appreciated that the particles can have other suitable shapes. In one embodiment, the particles can have a diameter between about 50 μ m and
15 100 μ m.

In addition to, or instead of, being used to potentially modify the physical characteristics of the tip member, the provision of the metallic particles also result in the tip member being detectable by fluoroscopy and X-ray techniques. This provides another means for the surgeon to monitor the
20 placement and position of the tip member during or after insertion of the electrode array in the body, such as in the cochlea.

When the elongate member is in the first configuration, the tip member is preferably substantially straight and, more preferably, straight.

In a further embodiment, the tip member can be coated with a
25 lubricious material. The lubricious material can be a bioresorbable or non-bioresorbable material.

The tip member can be formed from, or incorporate as a portion thereof, a bioresorbable material. The presence of the bioresorbable material preferably results in the flexibility of the tip member increasing on insertion
30 of the tip member into the body, such as the cochlea. The bioresorbable material in the tip member can be selected from the group consisting of polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA).

In another embodiment, the tip member can be formed from, or
35 incorporate as a portion thereof, a polymeric coating which becomes softer,

and so increases in resilient flexibility, in the presence of moisture or body heat.

The tip member preferably has a length from its distal end to its proximal end in the range of about 0.3 to 4mm, more preferably about 1.0 to 3mm. The diameter of the tip member can be substantially constant for a majority of its length or can vary in diameter. The tip member can be substantially cylindrical, cylindrical, or non-cylindrical for a majority of its length. At the distal end, the diameter preferably gradually decreases to form a rounded end. The maximum diameter of the tip member is preferably about 0.55mm.

In one embodiment, the tip member can be solid. In another embodiment, the tip member can have an external wall defining a cavity. In one embodiment, the cavity can have a diameter greater than that of the receiving portion of the body of the elongate member. In a further embodiment, the cavity can extend from the proximal end towards the distal end of the tip member. The cavity can decrease in diameter away from the proximal end. The cavity can be in communication with a distal end of the receiving portion of the body of the elongate member. In a further embodiment, the stiffening means can extend into the cavity when positioned within the device or assembly according to the respective aspects of the present invention. In a preferred embodiment, the tip member can move relative to the stiffening means when it extends into the cavity of the tip member.

In general, the tip could be made of a combination of materials arranged in a variety of geometries depending on the specific design goal. The outside shape and size of the tip can also be made in a variety of forms depending on the design goal.

In a further embodiment, the bioresorbable material of the stiffening element is selected from the group consisting of polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA). Other materials could also be used which provide the characteristics required for the particular application.

The outer layer can be in turn surrounded by another layer. In a further embodiment, the outer layer can be formed from a biocompatible material. In one embodiment, the outer layer can be formed from a material that has a relatively higher degree of resilient flexibility than the elongate

member. In another embodiment, the material of the outer layer can have a resilient flexibility identical to that of the elongate member. In a preferred embodiment, the outer layer is formed from the same material as the elongate member.

- 5 The outer layer can be bonded to the elongate member. In another embodiment, the outer layer can be integrally formed therewith.

 In one embodiment, the stiffening element can comprise a longitudinal quasi-stylet disposed in a lumen extending within the elongate member. In one embodiment, the lumen can be cylindrical or any other suitable shape
10 and also can have an opening formed therein, providing the fluid ingress means of the assembly.

 The opening is preferably at an end of the lumen distal the first end of the elongate member. In this embodiment, the opening can be closed by a closure means adapted to seal the opening of the lumen.

- 15 The closure means can comprise a plug adapted to be inserted into the lumen and to form a seal therewith. The plug can have a frusto-conical outer wall adapted to seal with the wall of the lumen on insertion. The plug in this embodiment can be formed from a resiliently flexible material such as silicone or polyurethane. Alternatively, the plug could be of any suitable
20 shape and could also be formed from a stiff plastic such as polytetrafluoroethylene (PTFE) or a metal such as platinum or stainless steel.

 In another embodiment, the closure means can comprise a cap adapted to seal the opening of the lumen. In one embodiment, the cap can have a top adapted to seal the opening and a skirt depending therefrom. The skirt can
25 have an engagement means formed on an outer surface thereof adapted to engage with the inner surface of the lumen on mounting of the cap to the lumen. In this embodiment, the inner surface of the lumen can have an engagement means complementary to that on the outer surface of the skirt of the cap. The engagement means on the skirt can comprise a screw thread
30 adapted to engage with a corresponding screw thread on the inner cylindrical surface of the lumen.

- In another embodiment, the stiffening element can comprise a sheath that at least partially surrounds the elongate member. In this embodiment, the sheath preferably fully envelops the elongate member. In this
35 embodiment, an annular channel can be formed in the elongate member to receive the sheath. Such an annular channel can have an annular opening at

an end distal the first end of the elongate member. The annular opening of the channel can be closed by a suitably shaped plug or cap.

In another embodiment, the opening of the lumen or channel can be closed by a sealing layer bonded to the elongate member. The sealing layer
5 can be formed from a layer of silicone material that is used to close the opening following placement of the stiffening element within the elongate member. In another embodiment, the elongate member can be fabricated such that the closure means is provided by an extension of the outer layer over the opening of the lumen or channel or a drop of silicone or other
10 sealing material over the opening.

In the latter case, the closure means is preferably removable to form an opening by slicing the sealing layer or outer layer extension with a blade, such as that provided by a pair of scissors, to allow ingress of fluid into the lumen or channel.

In a further embodiment, a plurality of openings, comprising the fluid ingress means, can be formed in the outer layer. In one embodiment, the openings can be disposed along the length of the outer layer. In one
15 embodiment, the openings can be equally spaced along the length of the outer layer. In a preferred embodiment, the openings can comprise slits formed in the outer layer. The slits preferably slow but do not prevent ingress of fluid through the outer layer to the stiffening element. In a further embodiment, the slits can be formed in a lateral surface of the elongate member such that on the commencement of curvature of the elongate member, the slits are caused to at least partially open and allow fluid ingress into the elongate
20 member.
25

The slits can be formed to all allow substantially the same or the same rate of ingress of fluid through the outer layer. In another embodiment, at least one slit can allow a different rate of progress of fluid through the outer layer compared to the other slits. In a still further embodiment, each slit can
30 allow a different rate of progress of fluid through the outer layer compared to the other slits formed therein.

In one embodiment, the slit most distal the first end of the elongate member can allow a greater rate of fluid ingress through the outer layer than its adjacent slit positioned closer to said first end or vice versa. As such, the
35 bioresorbable material beneath this slit preferably begins to dissolve or soften before the remainder of the stiffening element so allowing the elongate

member to begin to firstly move from its first configuration to its second configuration at or adjacent the position of this most distal or most proximal slit.

The rate of progress provided by each slit can follow this pattern along
5 the length of the device towards the first end, with the next closer slit to the first end providing a relatively lesser rate of ingress than its adjacent more distal slit. This pattern results in the bioresorbable material dissolving or softening from an end distal the first end towards an end closer to the first end or vice versa. Where the first configuration is straight and the second
10 configuration is curved, the elongate member begins to curve distal the first end and then continues to further adopt the curved configuration as the stiffening element dissolves or softens towards the first end or vice versa.

In one embodiment, the slits or other fluid ingress means can be sealable with a bioresorbable material. The bioresorbable material preferably
15 softens and/or dissolves on exposure to a fluid, such as cochlear fluid, to allow ingress of the fluid into the elongate member. In this embodiment, the slits or other fluid ingress means can be sealed with the same or a different quantity and/or the same or different thicknesses of bioresorbable material. Variations in thickness and/or quantity of the bioresorbable material provide
20 a means of varying the rate of ultimate dissolution of the stiffening element of the device.

In another embodiment, the fluid ingress means can comprise regions of silicone having a thickness less than that of the remainder of the outer layer. Due to the reduced thickness of these regions, the fluid passes through
25 the fluid ingress means more quickly than the remainder of the outer layer. The thickness of the fluid ingress regions can be varied to suit the desired rate of dissolution/softening of the stiffening element required by the application. Different regions can have different thickness as required. For example, a region distal the first end of the elongate member can have a
30 thickness that is thinner than that of a region closer to the first end.

In a further embodiment, at least a portion of an outer surface of the elongate member can have a coating of a lubricious material. In one embodiment, a substantial portion or the entire outer surface of the elongate member can have a coating of the lubricious material.

35 In this embodiment, the lubricious material can be selected from the group comprising polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic

acid (PLA) and polyglycolic acid (PGA). It is envisaged that other similar materials could also be used.

In a further aspect, the present invention comprises a method of implanting a tissue-stimulating device or cochlear electrode assembly device
5 as defined herein in a body of an implantee.

In this aspect, the method can comprise a step of accessing the implantation site and then a step of inserting the device. Prior to insertion, the device is preferably substantially straight or straight. On insertion, the device can adopt an intermediate configuration (as defined herein). Either
10 prior to full insertion or following full insertion, the device preferably adopts its second configuration.

Once implanted, the electrodes can receive stimulation signals from a stimulator means. The stimulator means is preferably electrically connected to the elongate member by way of an electrical lead. The lead can include the
15 one or more wires extending from each electrode of the array mounted on the elongate member.

In one embodiment, the lead can extend from the elongate member to the stimulator means or at least the housing thereof. In one embodiment, the lead is continuous with no electrical connectors, at least external the housing
20 of the stimulator means, required to connect the wires extending from the electrodes to the stimulator means. One advantage of this arrangement is that there is no requirement for the surgeon implanting the device to make the necessary electrical connection between the wires extending from the electrodes and the stimulator means.

25 The stimulator means is preferably positioned within a housing that is implantable within the implantee. The housing for the stimulator means is preferably implantable within the bony well in the bone behind the ear posterior to the mastoid.

When implantable, the housing preferably contains, in addition to the
30 stimulator means, a receiver means. The receiver means is preferably adapted to receive signals from a controller means. The controller means is, in use, preferably mounted external to the body of the implantee such that the signals are transmitted transcutaneously through the implantee.

Signals can preferably travel from the controller means to the receiver
35 means and vice versa. The receiver means can include a receiver coil adapted to receive radio frequency (RF) signals from a corresponding

transmitter coil worn externally of the body. The radio frequency signals can comprise frequency modulated (FM) signals. While described as a receiver coil, the receiver coil can preferably transmit signals to the transmitter coil which receives the signals.

5 The transmitter coil is preferably held in position adjacent the implanted location of the receiver coil by way of respective attractive magnets mounted centrally in, or at some other position relative to, the coils.

The external controller can comprise a speech processor adapted to receive signals output by a microphone. During use, the microphone is
10 preferably worn on the pinna of the implantee, however, other suitable locations can be envisaged, such as a lapel of the implantee's clothing. The speech processor encodes the sound detected by the microphone into a sequence of electrical stimuli following given algorithms, such as algorithms already developed for cochlear implant systems. The encoded sequence is
15 transferred to the implanted stimulator/receiver means using the transmitter and receiver coils. The implanted stimulator/receiver means demodulates the FM signals and allocates the electrical pulses to the appropriate attached electrode by an algorithm which is consistent with the chosen speech coding strategy.

20 The external controller further comprises a power supply. The power supply can comprise one or more rechargeable batteries. The transmitter and receiver coils are used to provide power via transcutaneous induction to the implanted stimulator/receiver means and the electrode array.

While the implant system can rely on external componentry, in another
25 embodiment, the controller means, including the microphone, speech processor and power supply can also be implantable. In this embodiment, the controller means can be contained within a hermetically sealed housing or the housing used for the stimulator means.

Brief Description of the Drawings

30 By way of example only, preferred embodiments of the invention are now described with reference to the accompanying drawings, in which:

Fig. 1 is a simplified cross-sectional view of one embodiment of an electrode assembly according to the present invention;

Fig. 2 is a simplified cross-sectional view of another embodiment of an
35 electrode assembly according to the present invention;

Fig. 3 is a diagrammatic view of the assembly of Fig. 1 being inserted in to the scala tympani;

Fig. 4 is a diagrammatic view of the assembly of Fig. 1 deployed in the scala tympani;

5 Fig. 5 is a simplified cross-sectional view of another embodiment of an electrode assembly according to the present invention; and

Figs. 6a-6d depict alternative tip structures for the electrode assembly depicted in Fig. 5.

Preferred Mode of Carrying Out the Invention

10 One embodiment of a cochlear implant electrode assembly is depicted generally as 10 in Figs. 1, 3 and 4.

The depicted electrode assembly 10 preferably has an electrical lead extending back to a stimulator/receiver housing. In considering this invention, it is to be understood that each electrode may have one or more
15 wires (not depicted) electrically connected thereto and extending from each respective electrode back through the lead to the stimulator/receiver. The use of a stimulator/receiver as described herein is known in the art and the present invention can be used with any such stimulator/receiver as known in the art.

20 The assembly 10 comprises an elongate electrode carrier member 11 having a plurality of electrodes 12 mounted thereon. For the purposes of clarity, the electrodes 12 depicted in Figs. 1, 2 and 5 are not necessarily shown to scale. The depicted elongate member 11 is preformed from a resiliently flexible silicone with memory and is preformed to a curved
25 configuration suitable for conforming with the inner wall of the scala tympani 30 of the cochlea as depicted in Fig. 4. The elongate member 11 has a first end 13, distal the lead, that is firstly inserted into the implantee on insertion of the assembly 10.

As depicted in Fig. 5, the elongate member 11 can have a tip member
30 29 integrally formed with its first end 13. The tip 29 is formed from the same silicone used to fabricate the elongate member 11 and, in the depicted embodiment, the material of tip member 29 has a resilient flexibility equal to that of the material used for the carrier member 11.

Possible alternative constructions for the tip member 29 are provided
35 in Figs. 6a-6d. As depicted in Fig. 6a, the tip member 70 can be solid and formed of an inner core 71 of relatively stiff material 71 and an outer layer 72

of relatively flexible material. The core 71 can taper in diameter over region 73 towards the distal end 21. The taper 73 causes the overall stiffness of the tip 70 to increase over the length of the taper 73 away from the distal end 21. The outer layer 72 can be formed of the same material as the remainder of the body of the elongate carrier member 11 or can be a different material.

As depicted in Fig. 6b, the tip member 40 can comprise a solid mass integrally formed to the first end 13 of the elongate carrier 11.

Still further and as depicted in Fig. 6c, the tip member 50 can comprise a solid mass 51 that is formed separately from the carrier member 11 and subsequently adhered thereto.

As depicted in Fig. 6d, the tip member 60 can comprise an elastomeric silicone material having a plurality of substantially spherical platinum particles 61 dispersed therethrough. The particles 61 have a diameter between about 50 μ m and 100 μ m. It will be appreciated that the particles 61 depicted in Fig. 6d are not drawn to scale.

In Fig. 6d, the particles 61 are depicted as substantially evenly dispersed through the tip member 60. In another embodiment, the particles could be non-evenly dispersed through the tip member. For example, the particles could increase in density away from the distal end 21 towards the proximal end of the tip member 60. By varying the density of the platinum particles 61, it is possible to vary the relative stiffness of the tip member 60.

In addition to, or instead of, being used to potentially modify the physical characteristics of the tip member, the provision of the metallic particles 61 also result in the tip member 60 being detectable by fluoroscopy and X-ray techniques. This provides another means for the surgeon to either monitor the placement and position of the tip member 60 during or after insertion of the electrode array 10 in an implantee's cochlea.

Disposed within a substantially cylindrical lumen 14 is a stylet-type element 15. This stylet-type element 15 differs from a conventional stylet in that it is formed from a bioresorbable polyacrylic acid (PAA) that is adapted to dissolve or soften on exposure to fluids to permit the elongate member 11 to take its preformed curved configuration. It will be appreciated that the stylet could be formed from other suitable bioresorbable materials. The stylet-type element 15 has a straight configuration and has a stiffness greater than that of the silicone making up the elongate member 11. Accordingly, the

stylelet-type element 15, when in position biases the elongate member 11 into a straight configuration as depicted in Figs. 1 and 3.

Overlaying the stylelet-type element 15 is an integral outer layer 16 of silicone material that surrounds and protects the stylelet-type element 15. In particular, the outer layer 16 serves to protect the stylelet-type element 15, at least for some time, from dissolution or softening due to exposure of the assembly to fluids, such as cochlear fluids, on insertion in the scala tympani 30.

As depicted in Fig. 1, the lumen 14 has an opening 17 at an end 18 distal the first end 13. In the embodiment depicted in Fig. 1, the opening 17 can be closed by a plug 19 that is adapted to seal the opening 17 of the lumen 14. While a frusto-conical plug is depicted in Fig. 1, other plug types can be envisaged. For example, and as is depicted in Fig. 2, the opening 17 can be sealed with a quantity 9 of silicone.

As an alternative to the plug 19 depicted in Fig. 1, the opening 17 of the lumen 14 can be closed by a sealing layer bonded to the elongate member 11. The sealing layer can be formed from a layer of silicone material that is used to close the opening 17 following placement of the stylelet-type element 15 within the lumen 14. In another alternative, the elongate member can be fabricated such that the closure is provided by an extension of the outer layer 16 over the opening 17 of the lumen 14.

In the latter case, the closure is preferably removed to form the opening 17 by slicing the sealing layer or outer layer extension with a blade, such as that provided by a pair of scissors, to allow ingress of fluid into the lumen 14.

An alternative embodiment of the electrode array is depicted generally as 20 in Fig. 2. In this embodiment, a plurality of transverse slits 21 are formed in the outer layer 16. The slits preferably slow but do not prevent ingress of fluid through the outer layer 16 to the stylelet-type element 15.

In the depicted embodiment, each slit 21 is adapted to allow a substantially equal rate of ingress of fluid into the lumen 14. It will be appreciated that the slit design could be modified such that different slits 21 allowed different rates of progress of fluid through the outer layer 16. For example, a slit 21 most distal the first end 13 could be adapted to allow a greater rate of fluid ingress through the outer layer 16 than its adjacent slit positioned closer to the first end 13. In this case, the bioresorbable material of the stylelet-type element 15 beneath this slit would begin to dissolve or

soften before the remainder of the stylet-type element 15 so allowing the elongate member 11 to begin to move from the straight configuration to its curved configuration at or adjacent the position of this most distal slit 21. In the depicted embodiment, each slit 21 can also be filled with a quantity of
5 bioresorbable material. In this case, each slit 21 can be filled with a different quantity or thickness of bioresorbable material so as to provide a means of controlling the location of and rate of dissolution of the stylet-type element 15.

The rate of progress provided by each slit 21 can follow this pattern
10 along the length of the elongate member 11 towards the first end 13, with the next closer slit 21 to the first end 13 providing a relatively lesser rate of ingress than its adjacent more distal slit 21. This pattern results in the bioresorbable material of the stylet-type element 15 dissolving or softening from an end distal the first end 13 towards an end closer to the first end 13.
15 As such, the straight elongate member 11 begins to curve distal the first end 13 and then continues to further adopt the curved configuration as the stylet-type element 15 dissolves or softens towards the first end 13 or vice versa.

As an alternative to the slits 21, the outer layer 16 of the elongate member 11 can be provided with one or more regions that more readily allow
20 ingress of bodily fluids, such as cochlear fluids. These regions can comprise regions of the outer layer 16 that have a thickness less than that of the remainder of the outer layer 16. Due to the reduced thickness of these regions, the fluid passes through the regions more quickly than the remainder of the outer layer 16. The thickness of the fluid ingress regions can be varied
25 to suit the desired rate of dissolution of the stylet-type element 15 required by the application. Different regions can have different thickness as required. For example, a region distal the first end 13 of the elongate member 11 can have a thickness that is thinner than that of a region closer to the first end 13, or vice versa. Such regions may also be formed by a matrix of pinholes or
30 other such structure to allow for a chosen rate of fluid ingress rather than slits.

In use, the substantially straight assembly 10 or 20 will initially be positioned at an entry to the scala tympani 30 as depicted in Fig. 3. At this point, in those embodiments where present, the plug 19, or quantity 9, can be
35 removed or a covering over the slits 21 peeled away to allow bodily fluids, such as cochlear fluids, to move into the lumen 14. Entry of the fluids into

the lumen 14 commences dissolution or softening of the stylet-type element 15.

As dissolution or softening is occurring, the assembly 10 can be carefully advanced into the scala tympani 30. Dissolution or softening of the stylet-type element 15 causes the assembly 10 to begin to adopt a curved configuration. As the assembly 10 continues to be advanced, it is preferably positioned as depicted in Fig. 4, with the electrodes 12 facing the modiola within the cochlea so that they are positioned as close as possible to the spiral ganglia thereof.

The control of the commencement of, and preferably the rate of, stylet dissolution provides the surgeon with greater control of the implantation procedure for the cochlear implant electrode assembly 10. The provision of greater control minimises the potential for trauma to the sensitive tissues inside the cochlea and also enhances the likelihood of successful placement of the assembly 10 at the first attempt.

While the preferred embodiment of the invention has been described in conjunction with a cochlear implant, it is to be understood that the present invention has wider application to other implantable electrodes, such as electrodes used with pacemakers.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

CLAIMS:

1. An implantable tissue-stimulating device comprising:
an elongate member having a plurality of electrodes mounted thereon
5 and having a first configuration selected to allow said member to be inserted into an implantee's body and at least a second configuration wherein said elongate member is adapted to apply a preselected tissue stimulation with the electrodes, said elongate member being made of a resiliently flexible first material;
10 a bioresorbable stiffening element having a configuration selected for biasing said elongate member into said first configuration, said stiffening element being made of a second material relatively stiffer than said first material and which dissolves or softens on exposure to a fluid to permit said elongate member to at least approach or adopt said second configuration; and
15 an outer layer surrounding the stiffening element, the layer being made of a material sufficiently resiliently flexible to allow said elongate member to at least approach or adopt said second configuration, the outer layer having a first rate of fluid ingress therethrough and having at least one fluid ingress means formed therein, the rate of fluid ingress through the fluid ingress
20 means being greater than the first rate of fluid ingress through the outer layer.
2. An implantable tissue-stimulating device of claim 1 wherein the second configuration of the elongate member is curved.
- 25 3. An implantable tissue-stimulating device of claim 2 wherein the elongate member adopts a spiral configuration when in the second configuration.
4. An implantable tissue-stimulating device of claim 1 wherein the fluid
30 is a body fluid of the implantee.
5. A cochlear implant electrode assembly comprising:
an elongate electrode carrier member having a plurality of electrodes mounted thereon and having a first configuration selected to allow said
35 member to be inserted into an implantee's cochlea and at least a second configuration wherein said elongate member is curved to match a surface of

said cochlea, said elongate member being made of a resiliently flexible first material;

a bioresorbable stiffening element having a configuration selected for biasing said elongate member into said first configuration, said stiffening
5 element being made of a second material relatively stiffer than said first material and which dissolves or softens on exposure to cochlear fluids to permit said elongate member to at least approach or adopt said second configuration; and

an outer layer surrounding the stiffening element, the layer being made
10 of a material sufficiently resiliently flexible to allow said elongate member to at least approach or adopt said second configuration, the outer layer having a first rate of cochlear fluid ingress therethrough and having at least one fluid ingress means formed therein, the rate of cochlear fluid ingress through the fluid ingress means being greater than the first rate of cochlear fluid ingress
15 through the outer layer.

6. A cochlear implant electrode assembly of claim 5 wherein the elongate member is preformed from a plastics material with memory and is preformed in the second configuration.

20

7. A cochlear implant electrode assembly of claim 5 wherein the elongate member has a first end that is firstly inserted into the implantee.

8. A cochlear implant electrode assembly of claim 5 wherein the first
25 configuration is at least substantially straight.

9. A cochlear implant electrode assembly of claim 5 wherein the elongate member is formed from a biocompatible material.

30 10. A cochlear implant electrode assembly of claim 5 wherein the bioresorbable material of the stiffening element is selected from the group comprising polyacrylic acid (PAA), polyvinyl alcohol (PVA), polylactic acid (PLA) and polyglycolic acid (PGA).

35 11. A cochlear implant electrode assembly of claim 5 wherein the outer layer is in turn surrounded by another layer formed from a material selected

from the group comprising a lubricious material and a non-lubricious material.

12. A cochlear implant electrode assembly of claim 11 wherein the outer
5 layer is formed from a biocompatible material.

13. A cochlear implant electrode assembly of claim 7 wherein the
stiffening element is positionable in a lumen extending within the elongate
member.
10

14. A cochlear implant electrode assembly of claim 13 wherein the lumen
has at least one opening at an end of the lumen distal the first end of the
elongate member, the opening being closable by a closure means.

15 15. A cochlear implant electrode assembly of claim 14 wherein the closure
means comprises a plug or cap.

16. A cochlear implant electrode assembly of claim 5 wherein the
stiffening element comprises a sheath that at least partially surrounds the
20 elongate member.

17. A cochlear implant electrode assembly of claim 16 wherein an annular
channel is formed in the elongate member to receive the sheath.

25 18. A cochlear implant electrode assembly of claim 14 wherein the opening
is closable by a sealing layer bonded to the elongate member.

19. A cochlear implant electrode assembly of claim 7 wherein a plurality of
the fluid ingress means in the form of slits are provided in the outer layer.

30 20. A cochlear implant electrode assembly of claim 19 wherein the slits are
formed so as to have substantially the same or the same rate of ingress of fluid
through the outer layer.

21. A cochlear implant electrode assembly of claim 19 wherein at least one slit has a different rate of progress of fluid through the outer layer compared to the other slits in the outer layer.

5 22. A cochlear implant electrode assembly of claim 21 wherein a slit most distal the first end of the elongate member allows a greater rate of fluid ingress through the outer layer than its adjacent slit positioned closer to said first end, such that the bioresorbable material of the stiffening element
10 of the stiffening element so allowing the elongate member to begin to firstly move from its first configuration to its second configuration at or adjacent the position of this most distal slit.

23. A cochlear implant electrode assembly of claim 22 wherein the rate of
15 ingress provided by each slit can follow this pattern along the length of the device towards the first end, with the next closer slit to the first end providing a relatively lesser rate of ingress than its adjacent more distal slit.

24. A cochlear implant electrode assembly of claim 19 wherein the slits are
20 sealable with a bioresorbable material.

25. A cochlear implant electrode assembly of claim 5 wherein a plurality of fluid ingress means are provided in the outer layer and each comprise regions of silicone having a thickness less than that of the remainder of the outer
25 layer.

26. A cochlear implant electrode assembly of claim 7 wherein a resiliently flexible tip member extends forwardly from the first end of the elongate member.

30

27. A cochlear implant electrode assembly of claim 26 wherein the tip member has a plurality of metallic particles dispersed therethrough.

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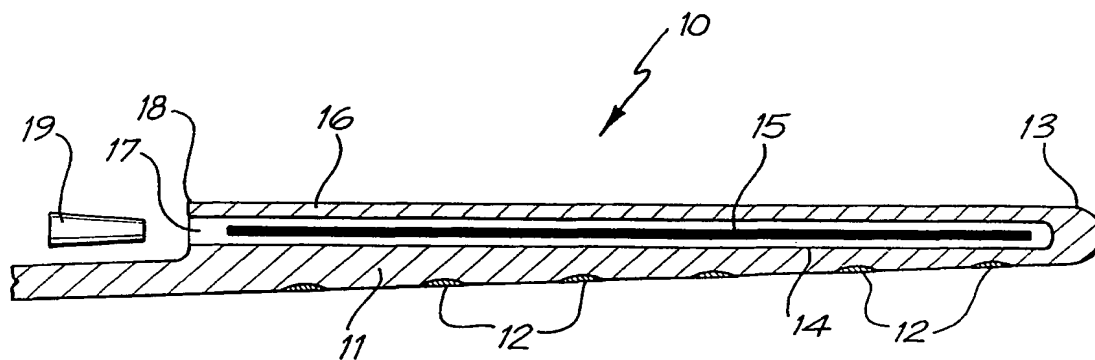


FIG. 1

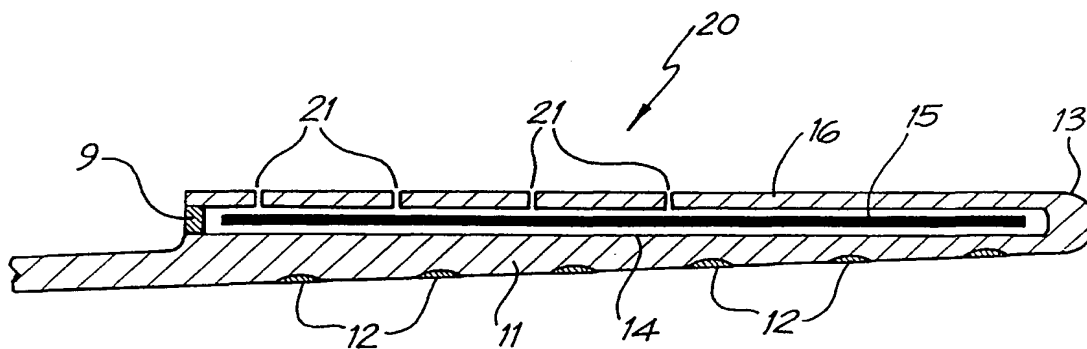


FIG. 2

2/3

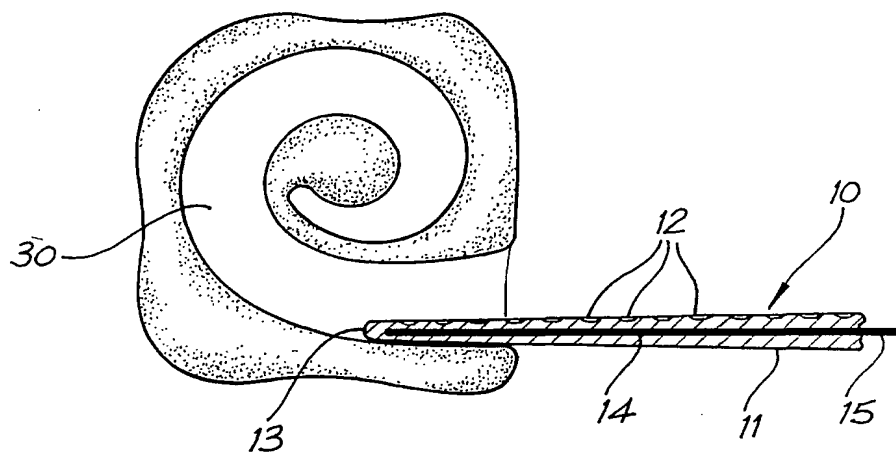


FIG. 3

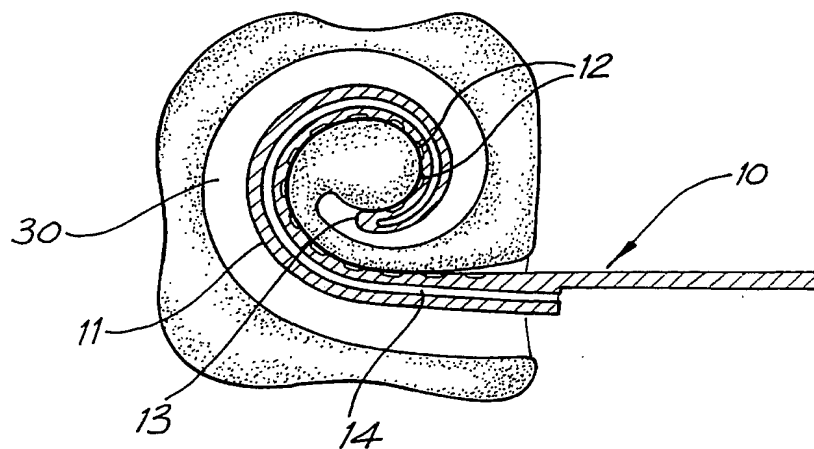


FIG. 4

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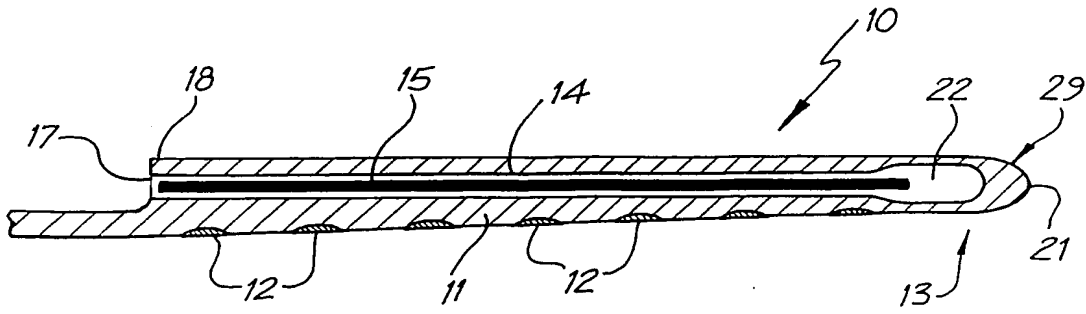


FIG. 5

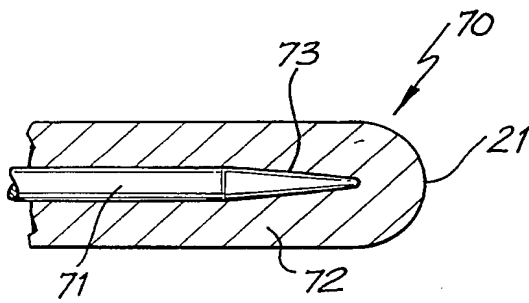


FIG. 6a

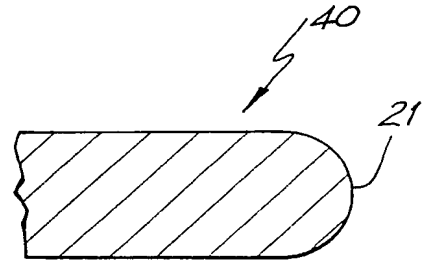


FIG. 6b

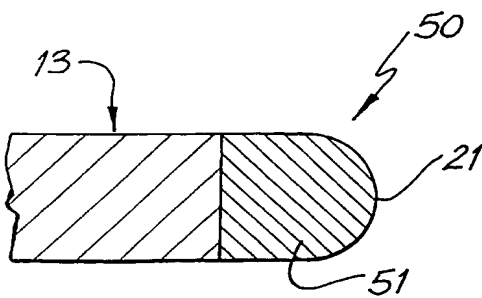


FIG. 6c

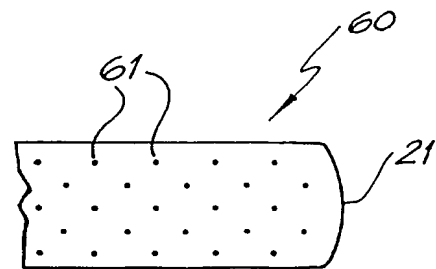



FIG. 6d

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU01/01231

A. CLASSIFICATION OF SUBJECT MATTER																						
Int. Cl. ⁷ : A61N 1/05 A61F 11/04																						
According to International Patent Classification (IPC) or to both national classification and IPC																						
B. FIELDS SEARCHED																						
Minimum documentation searched (classification system followed by classification symbols) SEE ELECTRONIC DATABASES CONSULTED																						
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched																						
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DWPI: tissue cochlear electrode implant prosthesis stiff shape configuration orientation spiral helix change vary alter differ																						
C. DOCUMENTS CONSIDERED TO BE RELEVANT																						
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.																				
A	WO 97/10784 A1 (COCHELAR LIMITED) 27 March 1997																					
A	EP 773037 A2 (PACESETTER AB) 14 May 1997																					
A	EP 783900 A2 (PACESETTER AB) 16 July 1997																					
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex																						
* Special categories of cited documents: <table border="0"> <tr> <td>"A"</td> <td>document defining the general state of the art which is not considered to be of particular relevance</td> <td>"T"</td> <td>later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"E"</td> <td>earlier application or patent but published on or after the international filing date</td> <td>"X"</td> <td>document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"L"</td> <td>document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"Y"</td> <td>document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"O"</td> <td>document referring to an oral disclosure, use, exhibition or other means</td> <td>"&"</td> <td>document member of the same patent family</td> </tr> <tr> <td>"P"</td> <td>document published prior to the international filing date but later than the priority date claimed</td> <td></td> <td></td> </tr> </table>			"A"	document defining the general state of the art which is not considered to be of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	"E"	earlier application or patent but published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	"O"	document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family	"P"	document published prior to the international filing date but later than the priority date claimed		
"A"	document defining the general state of the art which is not considered to be of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention																			
"E"	earlier application or patent but published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone																			
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art																			
"O"	document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family																			
"P"	document published prior to the international filing date but later than the priority date claimed																					
Date of the actual completion of the international search 22 October 2001		Date of mailing of the international search report 26 OCT 2001																				
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929		Authorized officer  MATTHEW FORWARD Telephone No : (02) 6283 2606																				

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU01/01231

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 783901 A2 (PACESETTER AB) 16 July 1997	

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU01/01231

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	97/10784	AU	35973/95	CA	2230595	US	5653742
		EP	971660				
EP	773037	JP	09-164208	US	5728148	SE	9601541
EP	783900	JP	09-187518	SE	9504675	US	579077
EP	783901	JP	09-187516	SE	9504677	US	5713943
							END OF ANNEX